

October 2010

News



# Nevada State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Medication Errors

An interesting study appearing in the *Journal of General Internal Medicine* found that fatal medication errors peak in July every year, possibly because of the inexperience of new medical residents. These fatal errors spiked only in counties with teaching hospitals and were 10% higher than the expected level. This finding is the result of an analysis of over 200,000 death certificates issued between 1979 and 2006 that listed "medication error" as the primary cause of death.

## Spice

*By Carmen Medina, PharmD Candidate, Idaho State University*

You have probably heard of spice but is it the same kind of "Spice" that your children are familiar with? We are not referring to oregano, paprika, or cumin; spice is the newest designer drug. Spice is a generic term referring to synthetic cannabinoids and cannabinomimetics. The Nevada State Board of Pharmacy will be addressing this class of designer drugs in upcoming meetings to evaluate whether these drugs should be categorized as Schedule I controlled substances.

The chemical components of Spice are HU-210, HU-211, JWH-018, JWH-073, CP 47, 497, and their homologues. The HU compounds are named after Hebrew University where they were discovered, hence the "HU." HU-210 is a structural and pharmacological analog of tetrahydrocannabinol (THC) and is up to 800 times more potent than the naturally occurring THC. This substance is currently classified as a Schedule I controlled substance federally.

Dr John W. Huffman (JWH), a professor at Clemson University, is credited with the synthesis of JWH-018 and JWH-073 and several hundred other similar compounds. Dr Huffman was working with the substances to isolate and research the cannabinoid type 1 (CB1) and type 2 (CB2) receptors in rats. In 2005, he published a scientific paper outlining the synthesis of the JWH-018, which

many believe is how these substances were exploited creating the new designer drug, Spice.

The JWH and CP compounds are structurally different from THC but act on the same receptors. These substances are up to 10 times more potent than naturally occurring THC. These compounds are sprayed onto a mixture of herbs resembling marijuana and sold in smoke shops, "head" shops, convenient stores, liquor stores, and online. The mixture is available in 1 g and 3 g packages labeled as incense or "herbal smoking mixture." On the package there is typically a warning such as "Not intended for human consumption." Spice blends are branded by up to 40 different names. Some common names include Black mamba, Ex-ese, K2, Skunk, Spice (diamond, gold, silver, etc), and Yucatan fire.

The structural differences of the JWH and CP compounds make it impossible to detect these substances on urinalysis. The only means of testing for these substances at this time requires a blood sample soon after consumption. GC-MS and/or LC-MS analysis of the blood is required. The biggest problem is that the substances must be in the machine's reference library for comparison to identify them in a sample. Because these are novel drugs and hard to identify they are not currently classified as controlled substances in most states.

There are risks with the consumption of Spice substances. There has been documented physical withdrawal from the substance after extended use. The half-life of synthetic cannabinoids is longer than THC and may accumulate over time. Several cases of adverse events have been reported by emergency department physicians in states where the substance is already regulated. Patients have presented with increased heart rate, increased pulse, and increased body temperature. Spice has not been tested on humans and the long-term effects on the human body are unknown.

Spice is currently illegal in several other countries. These countries include United Kingdom, Austria, Sweden, Canada, Ireland, Poland, Hungary, Germany, and Russia. Several states in the United States have enacted legislation to control Spice or the components of Spice, including Alabama, Arkansas, Georgia, Kansas, Kentucky, Louisiana, Missouri, North Dakota, and Tennessee. The US government has also banned these substances from use by any member of the armed forces.

The above-mentioned concerns, and the fact that these substances have no accepted medical use, have brought these substances

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## FDA Alert Regarding Administration of Oral Nimodipine Capsules

Food and Drug Administration (FDA) reminds health care providers that oral nimodipine capsules should be given only by mouth or through a feeding or nasogastric tube and should never be given by intravenous administration. FDA continues to receive reports of intravenous nimodipine use, with serious, sometimes fatal, consequences. Intravenous injection of nimodipine can result in death, cardiac arrest, severe falls in blood pressure, and other heart-related complications.

Nimodipine is a medication intended to be given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage and is only available as a capsule. Prescribing information warns against intravenous use of nimodipine and also provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients who are unable to swallow. The instructions recommend that the syringe used for withdrawal of capsule contents be labeled with "Not for IV Use." FDA will continue working with the manufacturers of nimodipine and with outside groups to evaluate and implement additional ways to prevent medication errors with this product.

An FDA Drug Safety Communication providing additional information for health care providers and patients is available at [www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm).

## FDA Approves Vaccines for the 2010-2011 Influenza Season

FDA approved vaccines for the 2010-2011 influenza season in the United States on July 30, 2010, and some manufacturers began shipping as early as mid-August. The seasonal influenza vaccine protects against three strains of influenza, including the 2009 H1N1 influenza virus, which caused the 2009 pandemic. Last year, two separate vaccines were needed to protect against seasonal flu and the 2009 H1N1 pandemic flu virus because the 2009 H1N1 virus emerged after production began on the seasonal vaccine, but this year, only one vaccine is necessary. The Centers for Disease Control and Prevention has published recommendations for annual influenza vaccination to include all people aged six months and older. The expanded recommendation is to take effect in the 2010-2011 influenza season. More information on the approved vaccine is available in an FDA news release available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220718.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220718.htm).

## FDA Alert Regarding Adverse Effects in Children After Unintentional Exposure to Evamist

FDA advises patients and health care providers of reports regarding adverse effects from Evamist® in children who may have been unintentionally exposed to the drug through skin contact with women using this product. Evamist contains estradiol, an estrogen hormone, and is a topical product, sprayed on the skin on the inside of the forearm between the elbow and the wrist. Children unintentionally exposed to Evamist may experience premature puberty. FDA is currently reviewing these reported adverse events and is working with the company to identify any factors that may contribute to unintended exposure and to evaluate ways to minimize the risk. FDA advises that patients should make sure that children are not exposed to Evamist and that children do not come into contact with any skin area where the drug was applied, and for

those who cannot avoid contact with children to wear a garment with long sleeves to cover the application site. Additional information for patients is provided in an FDA Drug Safety Communication available at [www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm).

## Safeguards to Implement with 'High Alert' Medications



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting [www.ismp.org](http://www.ismp.org). ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA Med-Watch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at [www.ismp.org](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

While most medications have a large margin of safety, a small number of drugs have a high risk of causing injury when they are misused. ISMP calls these "high-alert medications" to draw attention to this characteristic so that all involved in their use will treat them with the care and respect that they require. Errors may or may not be more common with these drugs than with the use of any others; however, the consequences of the errors are more devastating. For this reason, special considerations are required. These medications often need to be packaged differently, stored differently, prescribed differently, and administered differently than others. Examples of high-alert medications in community pharmacy include warfarin, insulin, methotrexate, and fentanyl patches. Whenever possible, "forcing functions" – methods that make it impossible for the drug to be given in a potentially lethal manner – should be developed and instituted. Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (eg, patient-specific indication must be entered if high-alert medication selected) is a forcing function.

An independent double-check of a high-alert medication is a procedure in which two pharmacists, alone and apart from each other, separately check each component of dispensing and verifying the high-alert medication, then compare results before giving it to the patient to self-administer. While technological solutions such as bar coding systems have great potential to detect human error, manual redundancies such as independent double checks still play an important role in error detection. Studies show that manual redundancies detect about 95% of errors. Independent double checks serve two purposes: to prevent a serious error from reaching a patient; and just as important, to bring attention to the systems that allow the introduction of human error. In retail pharmacies, with only one pharmacist per shift, the independent double check can be performed via a "will call" bag



check or by another pharmacist at the beginning of the next shift. If the medication has been dispensed, serious harm can be avoided or mitigated if the error is discovered within one or two doses.

The following information must be verified during the double-check process:

### **Comparison to prescriber's order:**

- ◆ Is this the prescribed drug?
- ◆ Is this the prescribed dose/strength/rate and route of administration?
- ◆ Is this the right patient (use two patient identifiers)?
- ◆ Is this the prescribed frequency?

### **Additional cognitive checks:**

- ◆ Does the drug's indication correspond to the patient's diagnosis?
- ◆ Is this the right drug formulation?
- ◆ Are dose calculations correct?
- ◆ Is the dosing formula (eg, mg/kg) used to derive the final dose correct?
- ◆ Is the prescribed dose/frequency/timing appropriate for this patient?
- ◆ Is the route of administration safe and proper for this patient?
- ◆ Has patient been educated on appropriate monitoring?

### **ASCO/FDA Program Provides Information on Expanded Access for IND Applications**

Developed in partnership with FDA, the American Society of Clinical Oncology (ASCO) offers an online interactive educational program to help providers understand FDA regulations regarding expanded access programs for individual-patient investigational new drug (IND) applications. The program provides an introduction from the viewpoint of various involved stakeholders, including physicians, FDA, industry, and patients and may assist pharmacists in providing patient counsel regarding expanded access.

This interactive module consists of:

- ◆ A thorough explanation of all expanded access programs available
- ◆ Links to key references and resources that are relevant to the slide content
- ◆ Selected virtual meeting presentations from ASCO Annual Meetings
- ◆ Helpful resources to use with patients

The program is available at <http://university.asco.org/ExpandedAccess> and participants may earn a certificate of participation or completion.

### **Rise in Prescription Pain Pill Abuse Documented in Latest SAMHSA Data**

Abuse of prescription pain medications continues to rise, according to the latest data from the Substance Abuse and Mental Health Services Administration (SAMHSA). The agency's Treatment Episode Data Set showed that the proportion of substance abuse treatment admis-

sions for individuals aged 12 and older rose 400% from 1998 to 2008. SAMHSA data also showed an increase in emergency room visits involving the non-medical use of a prescription narcotic pain reliever, which have tripled in proportion since 1998. SAMHSA Administrator Pamela S. Hyde, JD, stressed that the non-medical use of prescription pain relievers is now the second most prevalent form of illicit drug use. Hyde emphasized the importance of raising awareness about this public health threat and educating the public on the "critical importance of properly using, storing, and disposing of these powerful drugs" as reported in a SAMHSA press release available at [www.samhsa.gov/newsroom/advisories/1007140544.aspx](http://www.samhsa.gov/newsroom/advisories/1007140544.aspx).

### **USP Recommends Patient-Centered Standards for Prescription Labels**

To address the problem of patient misinterpretation of medication instructions, the United States Pharmacopeial Convention (USP) Health Literacy and Prescription Container Labeling Advisory Panel developed and recently released recommendations for standardizing the format, appearance, content, and language of prescription labels. The panel, on which the National Association of Boards of Pharmacy® (NABP®) participated, developed the patient-centered recommendations in response to a call for such standards from the Institute of Medicine. More details about the panel's recommendations are available in a USP press release at <http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=2WSh2u7neSpIu2bXW1HJ5VQ48HGFAOGH1NdNBeuPwJE%3d>.

### **Seven Pharmacy Organizations Respond to AMA Scope of Pharmacy Practice Document**

Seven national pharmacy organizations, including NABP, collaborated on the analysis and responded to the AMA Scope of Practice Data Series: Pharmacists, a document published by the American Medical Association (AMA) that describes the scope of the practice of pharmacy as viewed by the AMA authors. The pharmacy organizations identified significant opportunities for enhanced understanding by the AMA of contemporary pharmacy practice and urged the AMA to correct the identified issues noted in the document. AMA responded that meaningful dialogue will be pursued to examine ways pharmacists and physicians can collaboratively address the health care needs of patients. Collaborating on the pharmacy organizations' review and response were the American Pharmacists Association (APhA), American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, Accreditation Council for Pharmacy Education, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and NABP. The letter and materials sent to AMA are available at the following links from the APhA Web site:

- ◆ Recommendations: AMA Scope of Practice Data Series: Pharmacists, [www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=23148&TEMPLATE=/CM/ContentDisplay.cfm](http://www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=23148&TEMPLATE=/CM/ContentDisplay.cfm).
- ◆ Response Letter: AMA Scope of Practice Data Series: Pharmacists, [www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23149](http://www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23149).
- ◆ Scope of Contemporary Pharmacy Practice, [www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23150](http://www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23150).

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to the attention of several government agencies. The Nevada State Board of Pharmacy, in conjunction with the Attorney General's Workgroup on Methamphetamine Abuse, and at the request of the District Attorney of Douglas County, will begin working together to initiate the regulatory process to classify these compounds as Schedule I controlled substances.

### **Alcohol in Flavoring Agents**

Ethyl alcohol is a common ingredient in many liquid prescription and even nonprescription products. Many flavoring agents used in pharmacies contain alcohol as well, raising the question as to whether the patient (or patient's parent) should be informed of this fact. Parents often do not want their infant exposed to alcohol, no matter what the concentration.

To illustrate, chocolate flavoring available from one company at least, is 35% alcohol. Granted, only a small amount of flavoring is needed to accomplish the desired taste, resulting in probably less than 1% alcohol in the final product, but parents probably should be afforded that knowledge when counseling.

### **Electronic Prescriptions for Controlled Substances**

Drug Enforcement Administration (DEA) passed an interim final rule, which went into effect on June 1, 2010, regarding the electronic prescribing of controlled substances. The catch, however, is that DEA's rule requires that systems for sending and receiving controlled substance e-prescriptions must be "certified" by a "third party auditor" as meeting the security requirements specified in the rule. No such systems are certified to date, nor have any third-party entities been identified to conduct such audits and certification.

The bottom line for you as pharmacy practitioners is that if you receive an e-prescription for a controlled substance, you will need to either receive a written prescription as well or verify that prescription verbally before filling, treating the prescription as a telephoned prescription. The Board of Pharmacy has the regulations in place for the e-prescribing of controlled substances, with the exception of Schedule II controlled substances, so when the above described certification and auditing procedures are worked out, the Board is ready. The Board has elected to **not** allow Schedule II e-prescriptions at this time, opting to see how things play out with Schedule III through Schedule V e-prescriptions before taking that step.

### **50-Year Certificates**

The following pharmacists are to be congratulated for celebrating their golden anniversary by completing **50 years** of continuous licensure in Nevada: Carol Cigliano, Milo Draper, Phillip Sanders, Robert Zuckerman, John Rembert, Martin Honig, Herbert Mercer, Monte Marshall, Iwao Mochidome, Vahan Nishkian, Jr, Aubrey Swartz, and Thomas Beaston. Each will receive a special wall certificate to proudly display his or her accomplishment.

### **2010 Bowl of Hygeia**

The Nevada Bowl of Hygeia Committee has named Kathryn H. Craven (Katie) the 2010 recipient of the Bowl of Hygeia for 2010. A most deserving recipient, Katie has not only demonstrated service to the profession of pharmacy, but has devoted time, talent, and resources to a wide variety of interests including diabetes counseling and a long stint serving on the Board of Pharmacy. She will receive this most prestigious award in October at the Nevada Society of Health-System Pharmacists Annual Meeting in Las Vegas, NV. Congratulations, Katie!

### **2010 Renewal Reminder**

Please ensure that all employees whose licenses expire October 31, **2010** are renewed. On November 1, 2010 and after, if a license does not reflect an updated expiration date of **October 31, 2012**, then the licensee is not allowed to work. Select Verify a License on <http://bop.nv.gov> and verify the updated expiration date by searching through the Public License Search option. Please refer to the above Web site's Renewal of Licensure page for detailed information. All renewal forms were mailed to the address of record on September 15, 2010, allowing plenty of time to complete this requirement.

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